MCHL-CI (40) 12 April 2002

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Commander's Policy on Research Use of Human Pathological and Diagnostic Specimens – 02-14.

1. REFERENCE. AR 40-38, Clinical Investigation Program.

2. All clinical investigations involving the use of human pathological and diagnostic specimens must be approved by the Chief, Department of Pathology and Area Laboratory Services (DPALS) or the medical director of the appropriate Commander's laboratory. Particular attention will be given to the plan for handling of the specimens so that proper control of human tissue is maintained.

3. All human tissue specimens must remain under the control of the responsible pathologist until released for research and may be released only to investigators conducting approved clinical investigations. Existing specimens (ones obtained before the study begins) will be released by the pathologist under the conditions outlined in an approved study. Prospectively obtained specimens must remain under the control of the responsible pathologist until released under the conditions outlined in the approved study. The pathologist must determine that these conditions are met before releasing specimens for research use.

4. Research use of existing specimens (ones obtained before the study begins) usually does not require additional patient consent and may be exempted from committee review if the specimens are used in such a way that the donor cannot be identified directly or through identifiers linked to the donor.

5. Research use of specimens obtained after the study begins must be reviewed and approved by the WRAMC Clinical Investigation Committee. This includes all human tissue or body fluid obtained at autopsy or surgery as well as specimens obtained by clinical procedures and tissue or blood bank procedures. Informed consent must be given before obtaining any additional specimen that is required for routine patient care. Use of an excess or discarded portion of a specimen obtained for routine patient care generally requires prior informed consent. If such an excess or discarded sample is used in an unidentifiable manner, additional informed consent may not be required. The Human Use Committee will consider all uses of excess or discarded samples obtained at autopsy.

6. Questions regarding research use of human pathological and diagnostic specimens may be referred to Clinical Investigation as 782-6389.

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MICHAEL A. DUNN
COL(P), MC,
Commanding

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